DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 30 2002

Re: Novoseven
Docket No.: 99E-5112

The Honorable James. E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,784,950, filed by ZymoGenetics, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Novoseven, the human biological product claimed by the patent.

The total length of the regulatory review period for Novoseven is 3,954 days. Of this time, 2,904 days occurred during the testing phase and 1,050 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: May 29, 1988.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 1988.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: May 10, 1996.

   FDA has verified the applicant's claim that the product license application (BLA) for Novoseven (BLA 96-0597) was initially submitted on May 10, 1996.

3. The date the application was approved: March 25, 1999.

   FDA has verified the applicant's claim that BLA 96-0597 was approved on March 25, 1999.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Lisa B. Kole
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